Complete Summary

GUIDELINE TITLE

Prostatitis and chronic pelvic pain syndrome. In: Guidelines on the management of urinary and male genital tract infections.

BIBLIOGRAPHIC SOURCE(S)

Prostatitis and chronic pelvic pain syndrome. In: Grabe M, Bishop MC, Bjerklund-Johansen TE, Botto H, Çek M, Lobel B, Naber KG, Palou J, Tenke P. Guidelines on the management of urinary and male genital tract infections. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. p. 79-88. [51 references]

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

July 08, 2008 - Fluoroquinolones (ciprofloxacin, norfloxacin, ofloxacin, levofloxacin, moxifloxacin, gemifloxacin): A BOXED WARNING and Medication Guide are to be added to the prescribing information to strengthen existing warnings about the increased risk of developing tendinitis and tendon rupture in patients taking fluoroquinolones for systemic use.

COMPLETE SUMMARY CONTENT

** REGULATORY ALERT **

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

SCOPE

DISEASE/CONDITION(S)

- Prostatitis
- Chronic pelvic pain syndrome

Note: Traditionally, the term "prostatitis" has included both acute and chronic bacterial prostatitis, in which an infective organ is accepted, and the term "prostatitis syndrome" or more recently chronic pelvic pain syndrome (CPPS), in which no infective agent can be found and whose origin is multifactorial and in most cases obscure.

GUIDELINE CATEGORY

Diagnosis Prevention Treatment

CLINICAL SPECIALTY

Infectious Diseases Urology

INTENDED USERS

Physician Assistants Physicians

GUIDELINE OBJECTIVE(S)

- To assist urologists and physicians from other medical specialties in their daily practice
- To review documented or suspected bacterial infections of the prostate

TARGET POPULATION

Men with prostatitis or chronic pelvic pain syndrome

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

- 1. History and symptoms (including symptom questionnaire)
- 2. Clinical examination
- 3. Urinalysis and cultures of urine and expressed prostatic secretion (EPS)
- 4. Classification according to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) criteria
- 5. Perineal biopsy (not recommended)

- 6. Transrectal ultrasound (TRUS) (unreliable for diagnosis of prostatitis)
- 7. Laboratory evaluation of inflammatory markers in urine, EPS and ejaculate
- 8. Micturition chart, uroflowmetry and residual urine determination
- 9. Microscopy
- 10. Tests to rule out cancer, calculi, other obstruction, sexually transmitted diseases, as appropriate

Treatment

- 1. Antibiotics (fluoroguinolones, trimethoprim, tetracyclines, macrolides)
- 2. Route of administration
- 3. Duration of administration
- 4. Combination antibiotics and alpha-blockers (e.g., terazosin)
- 5. Terazosin, pentosan polysulphate sodium, or finasteride for symptom reduction
- 6. Intraprostatic injection of antibiotics if oral treatment fails (not recommended)
- 7. Surgery (transurethral resection of the prostate [TURP], transurethral needle ablation, radical prostatovesiculectomy (not generally recommended)
- 8. Other experimental treatment

MAJOR OUTCOMES CONSIDERED

- Reliability of diagnostic test
- Cure rate
- Time to cure

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

General Search Strategy

Up until 2007, the main strategy was to rely on the guidelines group members' knowledge and expertise on the current literature assuming that all, or almost all, relevant information would be captured.

In updates produced from 2008 onwards, a structured literature search will be performed for all guidelines but this search will be limited to randomized controlled trials and meta-analyses, covering at least the past three years, or up until the date of the latest text update if this exceeds the three-year period. Other excellent sources to include are other high-level evidence, Cochrane review and available high-quality guidelines produced by other expert groups or organizations. If there are no high-level data available, the only option is to include lower-level data. The choice of literature will be guided by the expertise and knowledge of the Guidelines Working Group.

Specific Strategy for This Guideline

For literature review, PubMed was searched for published meta-analyses, which were used as far as available. Otherwise there was a non-structured literature review process by the group members. Each member was responsible for one chapter (reporter).

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

Ia Evidence obtained from meta-analysis of randomized trials

Ib Evidence obtained from at least one randomized trial

IIa Evidence obtained from at least one well-designed controlled study without randomization

IIb Evidence obtained from at least one other type of well-designed quasi-experimental study

III Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports

IV Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Consensus Development Conference)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

General Methods Used to Formulate the Recommendations

- The first step in the European Association of Urology (EAU) guidelines procedure is to define the main topic.
- The second step is to establish a working group. The working groups comprise about 4-8 members, from several countries. Most of the working group members are academic urologists with a special interest in the topic. Specialists from other medical fields (radiotherapy, oncology, gynaecology, anaesthesiology etc.) are included as full members of the working groups as needed. In general, general practitioners or patient representatives are not part of the working groups. Each member is appointed for a four-year period, renewable once. A chairman leads each group.
- The third step is to collect and evaluate the underlying evidence from the published literature.
- The fourth step is to structure and present the information. All main recommendations are summarized in boxes and the strength of the recommendation is clearly marked in three grades (A-C), depending on the evidence source upon which the recommendation is based. Every possible effort is made to make the linkage between the level of evidence and grade of recommendation as transparent as possible.

Specific Methods Used for This Guideline

The members of the Urinary Tract Infection (UTI) Working Group of the European Association of Urologists (EAU) Health Care Office established the first version of these guidelines in several consensus conferences. The members of the current UTI Working Group of the EAU Guidelines Office updated the guidelines in several consensus conferences thereafter. The first draft of each chapter was sent to the committee members asking for comments, which were then considered, discussed and incorporated accordingly.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The formal agreement to each updated chapter was achieved by the European Association of Urology (EAU) working group at three plenary meetings: the first in Paris on 10 December 2004, the next in Istanbul on 15 March 2005, and finally in Florence on 22 October 2005. Each chapter was reviewed by three committee members (editorial group) for consistency and compatibility in two editorial meetings: one meeting took place in Straubing, 22-24 April 2005, and one in Stavern, 9-11 Sept 2005, and the chapters were revised accordingly.

There is no formal external review prior to publication.

The Appraisal of Guidelines for Research and Evaluation (AGREE) instrument was used to analyse and assess a range of specific attributes contributing to the validity of a specific clinical guideline.

The AGREE instrument, to be used by two to four appraisers, was developed by the AGREE collaboration (www.agreecollaboration.org) using referenced sources for the evaluation of specific guidelines. (See the "Availability of Companion Documents" field for further methodology information).

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The following is a summary of the recommendations for prostatitis and chronic pelvic pain syndrome. Refer to the original guideline for more detailed recommendations and discussion.

Levels of evidence (**Ia-IV**) and grades of recommendation (**A-C**) are defined at the end of the "Major Recommendations" field.

Bacterial prostatitis is a disease entity diagnosed clinically and by evidence of inflammation and infection localized to the prostate. According to the duration of symptoms, bacterial prostatitis is described as either acute or chronic, when symptoms persist for at least 3 months. It is recommended that European urologists use the classification suggested by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of the National Institutes of Health (NIH), in which bacterial prostatitis with confirmed or suspected infection is distinguished from chronic pelvic pain syndrome (CPPS). (The classification of prostatitis and CPPS according to NIDDK/NIH criteria is provided in the original quideline document.)

Acute bacterial prostatitis can be a serious infection. Parenteral administration of high doses of a bactericidal antibiotic is usually required, which may include a broad-spectrum penicillin, a third-generation cephalosporin, or a fluoroquinolone. All of these agents can be combined with an aminoglycoside for initial therapy. Treatment is required until there is defervescence and normalization of infection parameters (**IIIB**). In less severe cases, a fluoroquinolone may be given orally for 10 days (**IIIB**).

In chronic bacterial prostatitis, and if infection is strongly suspected in CPPS, a fluoroquinolone or trimethoprim should be given orally for 2 weeks after the initial

diagnosis. The patient should then be reassessed and antibiotics only continued if pre-treatment cultures are positive and/or the patient has reported positive effects from the treatment. A total treatment period of 4-6 weeks is recommended (**IIIB**).

Patients with CPPS are treated empirically with numerous medical and physical modalities. Despite the existence of some scientifically valid studies, no specific recommendations have been made until now. This has been because patients with CPPS probably represent a heterogeneous group of diseases and therapeutic outcome is always uncertain.

Table 1: Antibiotics in Chronic Bacterial Prostatitis*

Antibiotic	Advantages	Disadvantages	Recommendation		
Fluoroquinolones					
	 Favourable pharmacokinet ics Excellent penetration into the prostate Good bioavailability Equivalent oral and parenteral pharmacokinet ics (depending on the substance) Good activity against 'typical' and atypical pathogens and Pseudomonas aeruginosa In general, good safety profile 	Depending on the substance: Drug interactions Phototoxicity Central nervous system adverse events	Recommend		
Trimethoprim					
	 Good penetration into prostate Oral and parenteral 	No activity against Pseudomonas, some enterococci and some	Consider		

Antibiotic	Advantages	Disadvantages	Recommendation
	forms available Relatively cheap Monitoring unnecessary Active against most relevant pathogens	Enterobacteriaceae	
	7	Tetracyclines	
	 Cheap Oral and parenteral forms available Good activity against Chlamydia and Mycoplasma 	 No activity against Ps. aeruginosa Unreliable activity against coagulasenegative staphylococci, Escherichia coli, other Enterobacteriaceae, and enterococci Contraindicated in renal and liver failure Risk of skin sensitization 	Reserve for special indications
		Macrolides	
	 Reasonably active against Gram-positive bacteria Active against Chlamydia Good penetration into prostate Relatively nontoxic 	 Minimal supporting data from clinical trials Unreliable activity against Gramnegative bacteria 	Reserve for special indications

^{*}Adapted from Bjerklund Johansen TE, Grüneberg RN, Guibert J, Hofstetter A, Lobel B, Naber KG, Palou Redorta J, van Cangh PJ. The role of antibiotics in the treatment of chronic prostatitis: a consensus statement. Eur Urol 1998;34(6):457-466.

Definitions:

Levels of Evidence

- Ia Evidence obtained from meta-analysis of randomized trials
- **Ib** Evidence obtained from at least one randomized trial
- **IIa** Evidence obtained from at least one well-designed controlled study without randomization
- **IIb** Evidence obtained from at least one other type of well-designed quasi-experimental study
- **III** Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
- **IV** Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Grades of Recommendation

- A. Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomized trial
- B. Based on well-conducted clinical studies, but without randomized clinical studies
- C. Made despite the absence of directly applicable clinical studies of good quality

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for most of the recommendations (see "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate diagnosis and treatment of prostatitis or chronic pelvic pain syndrome (CPPS)

POTENTIAL HARMS

Side effects of antibiotics (drug interactions, phototoxicity, central nervous system adverse events, skin sensitization)

CONTRAINDICATIONS

CONTRAINDICATIONS

- In acute prostatitis, the prostate may be swollen and tender on digital rectal examination (DRE). Prostatic massage is contraindicated.
- Tetracyclines are contraindicated in renal and liver failure.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- The purpose of these texts is not to be proscriptive in the way a clinician should treat a patient but rather to provide access to the best contemporaneous consensus view on the most appropriate management currently available. European Association for Urology (EAU) guidelines are not meant to be legal documents but are produced with the ultimate aim to help urologists with their day-to-day practice.
- The EAU believe that producing validated best practice in the field of urology is a very powerful and efficient tool in improving patient care. It is, however, the expertise of the clinician which should determine the needs of their patients. Individual patients may require individualized approaches which take into account all circumstances and treatment decisions often have to be made on a case-by-case basis.
- The EAU working group believes that guidelines on prostatitis should not contain a set of minimum differential diagnostic examinations. An experienced urologist should decide which investigations are relevant for each individual patient.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

The European Association of Urology (EAU) Guidelines long version (containing all 19 guidelines) is reprinted annually in one book. Each text is dated. This means that if the latest edition of the book is read, one will know that this is the most updated version available. The same text is also made available on a CD (with hyperlinks to PubMed for most references) and posted on the EAU websites Uroweb and Urosource (www.uroweb.org/professional-resources/guidelines/ & http://www.urosource.com/diseases/).

Condensed pocket versions, containing mainly flow-charts and summaries, are also printed annually. All these publications are distributed free of charge to all (more than 10,000) members of the Association. Abridged versions of the guidelines are published in European Urology as original papers. Furthermore, many important websites list links to the relevant EAU guidelines sections on the association websites and all, or individual, guidelines have been translated to some 15 languages.

IMPLEMENTATION TOOLS

Pocket Guide/Reference Cards

For information about <u>availability</u>, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Prostatitis and chronic pelvic pain syndrome. In: Grabe M, Bishop MC, Bjerklund-Johansen TE, Botto H, Çek M, Lobel B, Naber KG, Palou J, Tenke P. Guidelines on the management of urinary and male genital tract infections. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. p. 79-88. [51 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2008 Mar

GUIDELINE DEVELOPER(S)

European Association of Urology - Medical Specialty Society

SOURCE(S) OF FUNDING

European Association of Urology

GUIDELINE COMMITTEE

Management of Urinary and Male Genital Tract Infections Guidelines Writing Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: M. Grabe (Chairman); M.C. Bishop; T.E. Bjerklund-Johansen; H. Botto; M. Çek; B. Lobel; K.G. Naber; J. Palou; P. Tenke

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Management of Urinary and Male Genital Tract Infections guidelines writing panel have provided disclosure statements of all relationships which they have and which may be perceived as a potential source of conflict of interest. This information is kept on file in the European Association of Urology Central Office database. This guidelines document was developed with the financial support of the European Association of Urology (EAU). No external sources of funding and support have been involved. The EAU is a non-profit organisation and funding is limited to administrative assistance, travel, and meeting expenses. No honoraria or other reimbursements have been provided.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the European Association of Urology Web site.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- EAU guidelines office template. Arnhem, The Netherlands: European Association of Urology (EAU); 2007. 4 p.
- The European Association of Urology (EAU) guidelines methodology: a critical evaluation. Arnhem, The Netherlands: European Association of Urology (EAU); 18 p.

The following is also available:

 Management of urinary and male genital tract infections. 2008, Ultra short pocket guidelines. Arnhem, The Netherlands: European Association of Urology (EAU); 2008 Mar. 17 p.

Print copies: Available from the European Association of Urology, PO Box 30016, NL-6803, AA ARNHEM, The Netherlands.

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on September 9, 2008. The information was verified by the guideline developer on December 8, 2008.

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